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10/644,106

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EXAMINER

SCHMIDT, EMILY LOUISE

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/644,106	Applicant(s) GIJSBERS ET AL.	
	Examiner Emily Schmidt	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25,27-31,33-35,37-43 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,25,27-31,33-35,37-43 and 45-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) in view of Adelman et al. (article in The Journal of General Physiology).

With regard to claim 23, Osterholm teaches a system for controlling epileptic seizures comprising: a) a brain fluid pumping mechanism (Figure 13 the pumping mechanism is taken to encompass all individual pumps contributing to the fluid pumping in this instance pump 111 is being considered, Col. 12 lines 17-19), having an input, coupled to a patient's brain for extracting brain fluid, and having an output (Figure 13 input is connected to the nutrient emulsion reservoir 100 - a source other than the patient's brain and an output connected to the chemical balancing unit 110); b) a fluid ion adjustment mechanism coupled to said output of said brain fluid pumping mechanism (In Figure 13 the ion adjustment mechanism is taken to be the chemical balancing unit 110, it is connected to the output of pump 111. Further in Figure 1, fluid from the brain is monitored for potassium and sodium ion concentrations - monitor 34 Col. 13 lines 46-50, in this diagram chemical balancing, taken to be ion adjustment, is at unit 12. Col. 15 lines 38-41 - sodium, potassium, calcium, magnesium, and chloride ions are balanced in the nutrient emulsion, it is taken that these ions would be balanced in the chemical balancing unit.), said fluid ion adjustment mechanism having an output from which modulated ion-content fluid is produced (Figure 13 - the balanced fluid is returned to the nutrient emulsion reservoir 100); c) a catheter,

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having an input coupled to the output of said ion adjustment mechanism and having an output inserted into a predetermined region of a patient's brain (Figure 13 - catheter 120 is connected to the nutrient emulsion reservoir which is the output for the fluid from the ion adjustment mechanism and is output into the patients brain, Col. 12 lines 30-31 and 34-35). Osterholm does not specifically disclose computer control with stored programming which controls the pumping mechanism to pump extracted fluid according to the program and measured electrical conductivity of the brain. However, Osterholm does disclose that the device uses pumping mechanisms which are preformed in a closed loop process (Col. 12 lines 14-16). Further Osterholm discloses that the device can be automatically shut down in response to an alarm (Col. 14 line 58- Col. 15 line 5, the chemical monitor, control, and alarm continuously monitor input values and when one of these values falls outside a pre-selected range the alarm can disable the system). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use computer control with stored programming to control the pump in the device of Osterholm because Osterholm discloses the pump using closed loop control and automatically monitoring and disabling the device in response to measured outputs. Further, it has been held the broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192. As stated above, the ion concentration in the device of Osterholm is monitored but Osterholm does not disclose measuring the electrical conductivity. However, Adelman et al. teach that ion concentration in the brain can be calculated using the ion conductivity (Pg. 603 lines 4-7 and 14-16). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to control the pumping based on electrical conductivity in the

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device of Osterholm because Adelman et al. teach that these values can be used to calculate ion concentration and would allow the ion concentrations to be properly balanced. Regarding the claims recitation that the instant invention change the electrical potential difference across a nerve cell membrane in epilepsy generating brain structure by changing the ion concentration in the modulated ion-content fluid to increase the potential different from -70 millivolts to -80 or more millivolts, the applicant is advised that, while the features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 44 USPQ2d 1429. In addition, it has been held by the courts that apparatus claims cover what a device is, not what a device does. *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 15 USPQ2d 1525 (Fed. Cir. 1990). In this case, the device of Osterholm in view of Adelman et al. as rejected above recites the features of computer control which reads and executes stored program instructions to cause the pumping mechanism to pump extracted fluid according the program and measured electrical conductivity thereby disclosing (as detailed above) all the structural limitations required to perform the recited functional language. The device teaches the ability to change the ion concentration of the fluid and the recited structure would be able to change the potential difference.

3. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) and Adelman et al. (article in The Journal of General Physiology) as applied to claim 23 above, and further in view of Mayevsky (U.S. Patent 5,685,313).

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With regard to claim 25, Osterholm and Adelman et al. teach a system substantially as claimed. Osterholm does not teach an electrical probe to control the ion concentration. However, Mayevsky teaches a probe for insertion into the brain (Fig. 5, Col. 9 lines 35-40) which measures the ion concentration of the brain and outputs the data (Col. 9 lines 38-46, Col. 13 lines 2-3) and further that probes are known in the art for electrically measuring brain parameters (Col. 3 lines 3-5) such probes are used in conjunction with computer programs which measure and store data for analyzing (Col. 9 lines 44-46, Col. 13 lines 28-39). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an electrical probe and computer programming in the device of Osterholm to measure the electrical conductivity because Mayevsky teaches that such have proven successful in the art for measurement and output of brain function parameters including ion concentration. The device of Osterholm provides an output related to the measurement of ion-concentration of the brain as the fluid is monitored (Fig. 1 output monitor 34). Further, Osterholm teaches automatic chemical control which balances ion concentrations, Col. 14 lines 60-66, Col. 15 lines 38-41). Osterholm does not specifically disclose computer control. However, Osterholm does disclose an alarm which may automatically disable the system in the event of chemical imbalance (Col. 14 line 58-Col. 15 line 5, the chemical monitor, control, and alarm continuously monitor input values and when one of these values falls outside a pre-selected range the alarm can disable the system) and that chemical balancing is done in a closed loop process (Col. 12 lines 13-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use computer control with stored programming to control the pump in the device of Osterholm because Osterholm discloses automatic chemical balancing control. Further, it has been held the

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broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

4. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500), Adelman et al. (article in The Journal of General Physiology), and Mayevsky (U.S. Patent 5,685,313) as applied to claim 25 above, and further in view of applicant admitted prior art (AAPA).

With regards to claims 27 and 28, Osterholm discloses a system substantially as claimed. Osterholm does not specifically disclose using a membrane potential equation. However, AAPA discloses using the Goldman equation as a well-known equation for calculating the membrane potential (Page 9 [23] and as disclosed with reference to Kandel et al. [25]), therefore it would have been obvious to a person of ordinary skill in the art at the time the invention was made to calculate the ion concentration using such a membrane potential equation in the device in Osterholm because AAPA teaches it is an art recognized means for monitoring the ion concentration so the system can determine how the fluid needs to be chemically balanced.

5. Claims 29-31, 37, 39-43, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) in view of Skladnev et al. (US 6,845,264 B1) and Adelman et al. (article in The Journal of General Physiology).

With regard to claim 29 and 37, Osterholm teaches an apparatus for controlling epileptic seizures comprising: a) a fluid pumping mechanism (Figure 13 the pumping mechanism is taken

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to encompass all individual pumps contributing to the fluid pumping in this instance pump 111 is being considered, Col. 12 lines 17-19), having an input, coupled to a fluid source selected from the group consisting of a patient's brain and a source other a patient's brain, and having an output (Figure 13 input is connected to the nutrient emulsion reservoir 100 - a source other than the patient's brain and an output connected to the chemical balancing unit 110); b) a fluid ion adjustment mechanism coupled to said output of said fluid pumping mechanism (In Figure 13 the ion adjustment mechanism is taken to be the chemical balancing unit 110, it is connected to the output of pump 111. Further in Figure 1, fluid from the brain is monitored for potassium and sodium ion concentrations - monitor 34 Col. 13 lines 46-50, in this diagram chemical balancing, taken to be ion adjustment, is at unit 12. Col. 15 lines 38-41 - sodium, potassium, calcium, magnesium, and chloride ions are balanced in the nutrient emulsion, it is taken that these ions would be balanced in the chemical balancing unit.), said fluid ion adjustment mechanism having an output from which modulated ion-content fluid is produced (Figure 13 - the balanced fluid is returned to the nutrient emulsion reservoir 100); c) a catheter, having an input coupled to the output of said ion adjustment mechanism and having an output inserted into a predetermined region of a patient's brain (Figure 13 - catheter 120 is connected to the nutrient emulsion reservoir which is the output for the fluid from the ion adjustment mechanism and is output into the patients brain, Col. 12 lines 30-31 and 34-35), whereby modulated ion-content fluid can be injected into the brain; and d) the fluid pumping mechanism or fluid ion adjustment mechanism including means for adjusting the delivery of the modulated ion-content fluid (fluid is injected into the brain and continuously circulated and withdrawn, as it is withdrawn it is continuously monitored, controlled, and re-injected, Col. 6 line 26, Col. 14 lines 3-4, lines 58-60, claim 1 part

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d). The ion concentration in the device of Osterholm is monitored but Osterholm does not disclose means for measuring electrical conductivity. However, Skladnev et al. teach a probe used for measuring the electrical conductivity of tissue to determine the condition of the tissue (abstract). Additionally, Osterholm does not disclose the adjusted delivery is controlled based on the conductivity of the fluid. However, Adelman et al. teach that ion concentration in the brain can be calculated using the ion conductivity (Pg. 603 lines 4-7 and 14-16). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to control the re-injection based on electrical conductivity in the device of Osterholm using a probe as in Skladnev et al. because Adelman et al. teach that these values can be used to calculate ion concentration and would allow the ion concentrations to be properly balanced and the probe of Skladnev et al. has proven successful in the art for measuring the electrical conductivity of tissue and such measurements are beneficial in assessing the condition of tissue. Osterholm does not explicitly disclose computer control that reads and executes stored program instructions. However, Osterholm does disclose that the device uses pumping mechanisms which are preformed in a closed loop process (Col. 12 lines 14-16). Further Osterholm discloses that the chemical monitor, control, and alarm continuously monitor input values and when one of these values falls outside a pre-selected range the alarm can disable the system (Col. 14 line 58- Col. 15 line 5). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use computer control in the device of Osterholm because Osterholm discloses the pump using closed loop control and automatically monitoring and disabling the device in response to measured outputs. Further, it has been held the broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same

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result involves only routine skill in the art. *In re Venner*, 120 USPQ 192. Regarding the claims recitation that the instant invention change the electrical potential difference across a nerve cell membrane in epilepsy generating brain structure by changing the ion concentration in the modulated ion-content fluid to increase the potential different from -70 millivolts to -80 or more millivolts, the applicant is advised that, while the features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 44 USPQ2d 1429. In addition, it has been held by the courts that apparatus claims cover what a device is, not what a device does. *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 15 USPQ2d 1525 (Fed. Cir. 1990). In this case, the device of Osterholm in view of Skladnev et al. and Adelman et al. as rejected above recites the features of computer control which reads and executes stored program instructions to cause the pumping mechanism to pump extracted fluid according the program and measured electrical conductivity thereby disclosing (as detailed above) all the structural limitations required to perform the recited functional language. The device teaches the ability to change the ion concentration of the fluid and the recited structure would be able to change the potential difference.

With regard to claim 30, the catheter includes dual lumens (Figure 13 catheter 120, Col. 12 line 34). This catheter is being used in place of cannula 20a (Figure 1) which carries the input stream of the nutrient emulsion (Col. 12 lines 27-29) which carries the balanced fluid. This is input into a localized region of the patient's brain (Figure 1 lateral ventricle 20, Col. 12 line 33).

With regard to claim 31, in Figure 13 pump 107, taken to be part of the overall pumping mechanism, (Col. 11 lines 58-59) has variable speed delivery and establishes the final injection

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rate into the brain (Col. 12 line 17). The flow rate at which the fluid is pumped is monitored by unit 38 in Figure 1 and then predetermined by unit 18 in Figure 1 to establish a desired flow rate (Col. 14 lines 32-34).

With regard to claims 39 and 41, the device as rejected above is able to modulate the ion content of the fluid and would be capable to alter the voltage differential. Further, Osterholm does teach electrical monitoring of brain cells (Col. 14 lines 65-66) and Osterholm has predetermined which characteristics of brain cells are monitored and potentially any of the brain cells could be likely to be epileptic and Sklednev et al. teach using a probe for measuring electrical conductivity and Adelman et al. teach using electrical conductivity to alter ion concentration. The device is able to adjust the delivery of the ion-content fluid base upon measure electrical activity.

With regard to claim 40, Osterholm teaches that chemical balancing is done in a closed loop process (Col. 12 lines 13-14).

With regard to claim 42, the catheter comprises a tip with an arrangement of outlet holes disposed as a series of slits radially spaced around the tip (Col. 12 lines 50-52).

With regard to claim 43, the catheter provides the fluid to the lateral brain ventricle (Figure 1 ventricle 20, Col. 12 lines 30-35).

With regard to claim 45, the fluid is directly injected into the predetermined location of the lateral ventricle (Figure 1 ventricle 20, Col. 12 lines 30-35).

6. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) in view of Skladnev et al. (US 6,845,264 B1) and Adelman et

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al. (article in The Journal of General Physiology) as applied to claim 29 above, and further in view of Mayevsky (U.S. Patent 5,685,313).

With regard to claims 33 and 34, Osterholm teaches an apparatus substantially as claimed. Fluid is injected into the brain and continuously circulated and withdrawn, as it is withdrawn it is continuously monitored, controlled, and re-injected, Col. 6 line 26, Col. 14 lines 3-4, lines 58-60, claim 1 part d). The ion concentration in the device of Osterholm is monitored but Osterholm does not disclose an electrical probe to measure the ion-concentration. However, Mayevsky teaches a probe for insertion into the brain (Fig. 5, Col. 9 lines 35-40) which measures the ion concentration of the brain and output the data (Col. 9 lines 38-46, Col. 13 lines 2-3) and further that probes are known in the art for electrically measuring brain parameters (Col. 3 lines 3-5). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an electrical probe in the device of Osterholm to measure the electrical conductivity because Mayevsky teaches that such have proven successful in the art for measurement and output of brain function parameters including ion concentration. The device provides an output related to the measurement of ion-concentration of the brain as the fluid is monitored (Fig. 1 output monitor 34). Further, Osterholm teaches automatic chemical control which balances ion concentrations, Col. 14 lines 60-66, Col. 15 lines 38-41). Osterholm does not specifically disclose computer control to adjust delivery. However, Osterholm does disclose an alarm which may automatically disable the system in the event of chemical imbalance (Col. 15 lines 1-4) and that chemical balancing is done in a closed loop process (Col. 12 lines 13-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use computer control with stored programming to control the pump in the device of

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Osterholm because Osterholm discloses automatic chemical balancing control. Further, it has been held the broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

7. Claims 35, 38, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500), Skladnev et al. (US 6,845,264 B1) and Adelman et al. (article in The Journal of General Physiology) as applied to claim 29 above, and in view of applicant admitted prior art (AAPA).

With regards to claims 35 and 38, Osterholm discloses and apparatus substantially as claimed. Osterholm does not specifically teach using the Goldman equation. AAPA discloses using the Goldman equation as a well-known equation for calculating the membrane potential (Page 9 [23] and as disclosed with reference to Kandel et al. [25]), therefore it would have been obvious to calculate the ion concentration using this equation as in claims 35 and 38 in order to be able to monitor the concentration so the system can determine how the fluid needs to be balanced. With regard to claim 35 Osterholm teaches that pump 107 in Figure 13 (Col. 11 lines 58-59) has variable speed delivery and establishes the final injection rate into the brain (Col. 12 line 17). It would have been obvious to one of ordinary skill in the art that this would be a means for adjusting the delivery of the modulated ion-content fluid. Further, Osterholm teaches automatic chemical control which balances ion concentrations, Col. 14 lines 60-66, Col. 15 lines 38-41). Osterholm does not specifically disclose computer control to adjust delivery. However, Osterholm does disclose an alarm which may automatically disable the system in the event of

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chemical imbalance (Col. 15 lines 1-4) and that chemical balancing is done in a closed loop process (Col. 12 lines 13-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use computer control with stored programming to control the pump in the device of Osterholm because Osterholm discloses automatic chemical balancing control. Further, it has been held the broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

With regard to claims 46-48 AAPA discloses using ion exchange mechanisms of filtration and chemical treatment are well-know methods in the art for adjusting the ion concentration of a fluid (Page 6 [17]). While the device in Osterholm does not disclose what chemical balancing occurs to balance the ion concentration of the fluid it would have been obvious to a person of ordinary skill in the art to use filtering or chemical treatment to balance the ion concentration as it is an art recognized means for doing so in order to balance the fluid to the appropriate desired ion concentration.

8. Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500), Skladnev et al. (US 6,845,264 B1), and Adelman et al. (article in The Journal of General Physiology) as applied to claim 29 above, and further in view of Roberds et al. (US 2003/0215813 A1).

With regard to claim 39, Osterholm teaches an apparatus substantially as claimed. Osterholm does not specifically disclose that the voltage differential between the intra-cellular and extra-cellular fluid is modified to control epileptic seizures. However, Roberds et al. teach

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aberrations in ion channels can be responsible for epilepsy and stroke damage ([0003]) ion channel gates are influenced by the membrane potential ([0003]) which allows the proper flow of ions. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to produce a voltage differential in the device of Osterholm et al. to allow the brain to maintain proper function because Roberds et al. teach that maintaining the proper membrane potential and proper flow of ions is beneficial to prevent epilepsy and stroke damage.

With regard to claim 40, Osterholm teaches that chemical balancing is done in a closed loop process (Col. 12 lines 13-14).

With regard to claim 41, Osterholm teaches an apparatus substantially as claimed. Osterholm does not specifically disclose measuring the electrical activity of predetermined epileptic brains cells. Osterholm does teach electrical monitoring of brain cells (Col. 14 lines 65-66) and Osterholm has predetermined which characteristics of brain cells are monitored and potentially any of the brain cells could be likely to be epileptic. Further, Roberds et al. teach the maintaining the proper membrane potential is necessary for ion channels to work properly and that aberrations in ion channels can cause epilepsy or stroke damage ([0003]). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to measure the electrical activity of brain cells in the device of Osterholm because Roberds et al. teach such activity is indicative of problems relating to epilepsy and stroke damage.

9. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) in view of applicant admitted prior art (AAPA), Skladnev et al. (US 6,845,264 B1), and Adelman et al. (article in The Journal of General Physiology).

With regard to claim 49, Osterholm teaches a device which re-circulates fluid through the brain which is chemically balanced and filtered (Col. 14 lines 61-62, chemical balancing Fig. 1 unit 12). The device in Osterholm does not disclose what chemical balancing occurs to balance the ion concentration of the fluid. However, AAPA discloses that using ion exchange mechanisms of filtration and chemical treatment are well-know methods in the art for adjusting the ion concentration of a fluid (Page 6 [17]). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use filtering or chemical treatment to balance the ion concentration in the device of Osterholm because AAPA teaches it is an art recognized means for doing so in order to balance the fluid to the appropriate desired ion concentration. In the device of Osterholm fluid is injected into the brain and continuously circulated and withdrawn, as it is withdrawn it is continuously monitored and controlled (Col. 6 line 26, Col. 14 lines 3-4, lines 58-60, claim 1 part d). It is pumped into a localized region of the patient's brain in the lateral ventricle (Figure 1 ventricle 20, Col. 12 lines 30-35). Further, in the device of Osterholm fluid that was injected into the brain circulates and then is withdrawn and monitored, effectively the brain fluid proximate to the region where the fluid in Osterholm is injected is monitored (Col. 13 lines 44-47). Fluid is injected into the brain and continuously circulated and withdrawn, as it is withdrawn it is continuously monitored, controlled, and re-injected (Col. 6 line 26, Col. 14 lines 3-4, lines 58-60, claim 1 part d). Osterholm teaches the fluid is monitored for ion concentrations but Osterholm does not disclose a means for monitoring the electrical conductivity. However, Skladnev et al. teach a probe used for measuring the electrical conductivity of tissue to determine the condition of the tissue (abstract). Additionally, Osterholm does not disclose the delivery is controlled based on the conductivity of the fluid.

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However, Adelman et al. teach that ion concentration in the brain can be calculated using the ion conductivity (Pg. 603 lines 4-7 and 14-16). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to control the delivery based on electrical conductivity in the device of Osterholm using a probe as in Skladnev et al. because Adelman et al. teach that these values can be used to calculate ion concentration and would allow the ion concentrations to be properly balanced and the probe of Skladnev et al. has proven successful in the art for measuring the electrical conductivity of tissue and such measurements are beneficial in assessing the condition of tissue. Osterholm does not explicitly disclose computer control that reads and executes stored program instructions. However, Osterholm does disclose that the device uses pumping mechanisms which are preformed in a closed loop process (Col. 12 lines 14-16). Further Osterholm discloses that the chemical monitor, control, and alarm continuously monitor input values and when one of these values falls outside a pre-selected range the alarm can disable the system (Col. 14 line 58- Col. 15 line 5). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use computer control in the device of Osterholm because Osterholm discloses the pump using closed loop control and automatically monitoring and disabling the device in response to measured outputs. Further, it has been held the broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192. Regarding the claims recitation that the instant invention change the electrical potential difference across a nerve cell membrane in epilepsy generating brain structure by changing the ion concentration in the modulated ion-content fluid to increase the potential different from -70 millivolts to -80 or more millivolts, the applicant is advised that, while the

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features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 44 USPQ2d 1429. In addition, it has been held by the courts that apparatus claims cover what a device is, not what a device does. *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 15 USPQ2d 1525 (Fed. Cir. 1990). In this case, the device of Osterholm in view of Skladnev et al. and Adelman et al. as rejected above recites the features of computer control which reads and executes stored program instructions to cause the pumping mechanism to pump extracted fluid according the program and measured electrical conductivity thereby disclosing (as detailed above) all the structural limitations required to perform the recited functional language. The device teaches the ability to change the ion concentration of the fluid and the recited structure would be able to change the potential difference.

Response to Amendment

10. The amendments to the claims have been entered and are sufficient to overcome the rejections under 35 U.S.C. 101.

Response to Arguments

11. Applicant's arguments filed May 03, 2010 have been fully considered but they are not persuasive. The Examiner finds that Osterholm in view of Adelman et al. as rejected above teach a computer control that reads and executes stored program instructions that cause the pumping mechanism to pump the extracted fluid according to the program and measured

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electrical conductivity of the brain fluid to change the electrical potential difference across a nerve cell membrane in epilepsy generating brains cells by changing the ion concentrations. The only part of the recitation the Examiner finds the prior art references to lack is specifically that the potential difference is increased form -70 millivolts to -80 or more millivolts. As the device as rejected is able to change the ion concentration in response to measured electrical conductivity it would be able to change the potential difference of the fluid by the recited amounts. And while the device of Osterholm does not change the ion concentration to specifically treat epilepsy it is able to carry out the recited fluid adjustment. Features of Osterholm which indicate the device is controlled via stored programming are indicated above, for example, the device automatically shuts off or signals alarms. Additionally, Applicant's specification suggests that it is known to manipulate brain fluid potential so that cells are hyper-polarized to decrease the likelihood of an epileptic seizure (Pg. 3 [05]).

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Schmidt/

Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767